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Award Number:
W81XWH-09-1-0217

TITLE:
Next Generation Education for Prevention: Defining Educational Needs, Attitudes, Concerns, Life Plans of 18 to 24 Year Old Daughters of *BRCA1/2* Mutations Carriers

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REPORT DATE:
March 2011

TYPE OF REPORT:
Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

X Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
14-MAR-2011	Annual	15 Feb 2010 - 14 Feb 2011

4. TITLE AND SUBTITLE
Next Generation Education for Prevention: Defining Educational Needs, Attitudes, Concerns, Life Plans of 18 to 24 Year Old Daughters of *BRCA1/2* Mutations Carriers

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-09-1-0217

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Dana-Farber Cancer Institute, Inc.

Boston, MA 02215

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Material Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The goals of this study are to 1.) Describe in-depth the knowledge, attitudes, health behaviors, and life plans of a cohort of 40 daughters, ages 18-24 years, of mothers who are *BRCA1/2* mutation carriers, and 2.) Define specific health educational, psychological, insurance and medical needs of this population. We will then outline a health educational intervention targeted to identified needs of our target group. Our major data source will be the 40 in-depth, qualitative (semi-structured), telephone interviews we will conduct with 18-24 year old daughters of *BRCA1/2* mutation carriers. To date we have ascertained nearly 200 eligible mothers (many with multiple eligible daughters) at 3 Harvard teaching hospitals, gotten IRB approvals and an NIH Certificate of Confidentiality, developed and pre-tested our questionnaire and interview schedule and initiated piloting of these materials. We have also, however, encountered significant administrative hurdles which took longer than anticipated to clear, leaving us behind our original timeline. We anticipate catching up over the next year and, as originally anticipated, having quantitative findings and a qualitative report by the end of Year 2 when we expect to have conducted, transcribed, coded and analyzed 40 interviews with young adult daughters of *BRCA1/2* mutation carriers.

15. SUBJECT TERMS
Genetic testing, breast cancer, prevention, BRCA1/2, education

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Karen Wylie, Ph.D.
U	U	U	UU	32	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

	Page
Introduction	4
Body	4
Key Research Accomplishments	8
Reportable Outcomes	8
Conclusion	9
References	9
Appendices	10

INTRODUCTION: Data from this study has the potential to answer an important question about genetic testing, i.e. what do those who are told by a relative, especially those informed as children, understand about hereditary breast cancer and what are the gaps or misperceptions in their knowledge? Are the gaps sufficient to cause us to challenge the present mode of spreading family information about hereditary risk by word of mouth through relatives? Are there ethical, more flexible models professionals we might adopt? We know that not all relatives are informed and that while much telling occurs soon after testing, in some cases, it is delayed many years. We know that parents who are mutation carriers worry most about impact on their children, yet we know little or nothing about what those children understand. We believe that an educational intervention to help inform young women as they come to an age at which they can make independent decisions about genetic testing would be valuable and potentially life-saving in its impact, encouraging them to seek genetic counseling and testing and to consider earlier and with more accurate information, the choices they face with regard to their hereditary cancer risk. The goals of this study are 1.) Describe in-depth the knowledge, attitudes, health behaviors, and life plans of a cohort of 40 daughters, ages 18-24 years, of mothers who are *BRCA1/2* mutation carriers, and 2.) Define specific health educational, psychological, insurance and medical needs of this population. Having this data will enable us to proceed towards development of a health educational intervention targeted to the identified needs of 18-24-year-old daughters of *BRCA1/2* mutation carriers, which will ultimately reduce mortality and morbidity. The major data source for this project are the 40 in-depth, qualitative (semi-structured), telephone interviews with 18-24 year old daughters of *BRCA1/2* mutation carriers which we have almost completed (39 complete). Additional quantitative data has been gathered from subjects including demographic and family history questions, the Brief Symptom Inventory-18, Impact of Event Scale and the Breast Cancer Genetic Testing Knowledge Scale. Subjects were selected for maximal diversity (family history, socio-economic status, cultural differences), from among the age-eligible daughters of the approximately 1000 *BRCA1/2*-positive women who have been tested at the DFCI, the Mass General Hospital (MGH), and the Beth Israel Deaconess Medical Center (BIDMC) between years 2000-2008.

BODY: We are pleased to report that we have completed the recruitment and enrollment of 39 daughters of *BRCA1/2* mutation carriers, ages 18-24. These 39 participants have completed both the quantitative assessment and qualitative interview components of our study. Recruitment of our 40th participant is in process at this time. This represents major progress in Year 2, after an initial year in which progress was limited due to IRB and access issues. It should be noted that the accessing and enrolling of these 39 daughters of *BRCA1/2*-positive mothers required a good deal of effort. One hundred and one mothers with one or more age-eligible daughters who had received genetic counseling and testing at one of three Harvard teaching hospitals were approached. Our pool was reduced to 80 mothers with potentially eligible daughters since 21 mothers were either found to be ineligible, were not able to be reached or had died. A total of 22 mothers declined to provide their daughter's contact information and an additional five mothers were unresponsive to multiple attempts to contact and are considered passive refusers. Fifty-three mothers (66%) provided contact information for their daughters. We invited 58 daughters to participate in our study (more than one daughter was recruited in five families when daughter #1 was either unresponsive to multiple attempts to contact (3) or had served as a pilot subject (2)). One daughter whose mother had very recently died became ineligible during the course of our inquiry. Two daughters actively declined and nine were not responsive to multiple contacts

and were assumed to be passive decliners. Forty-four daughters agreed to participate (5 pilots and 39 subjects) and were enrolled and completed both the quantitative and qualitative portions of the study for a participation rate of 77%. One additional daughter was consented and completed the quantitative assessment for our study but became unresponsive to attempts to contact for the purpose of scheduling her qualitative interview. This daughter's quantitative data will not be used in the data analysis phase of our study. We are currently in the midst of recruiting another daughter to serve as our 40th and final participant in the project.

The development of the coding book for the study is underway and will be completed by the end of Month 25. All but the last 3 interviews have either been transcribed or are being currently transcribed and expected to be completed next week. Transcription of the last 3 interviews is anticipated to be complete by the end of month 26. Coding of the interviews will be done by staff currently on board and will be complete by the end of Month 28. The analysis of the quantitative data and of some coded interviews will begin within a few weeks as soon as the 40th interview is completed in order to have material ready to present to the International Meeting on Psychosocial Aspects of Hereditary Cancer in Amsterdam. Our abstract entitled "What Do Young Adult Daughters of *BRCA1/2+* Mothers Know about Hereditary Risk; How Much Do They Worry?" has been accepted for oral presentation at that meeting.

COMPLETED TASKS:

Develop Interviews: Months 0 to 4
Develop questionnaire: Months 0 to 4
Get approval from DFCI/HCC and USAMRMC Institutional Review Boards: Months 2-8
Consult with and review materials with consultants: Months 1-7
Pilot Interviews and questionnaire: Months 13-14

Contact Mothers for permission to contact their daughters, Accrue and Consent Patients: Months 12-20 – We wrote to 101 mothers who are *BRCA1/2* mutation positive and who we believed had daughters 18-24 years of age requesting contact information for their daughter. Five mothers, we learned, were deceased. In eight cases, we did not have accurate or updated contact information for the mother. Eight mothers were ineligible (four did not have a child in our identified age range, five had not yet told their daughter about their test results, and one had a daughter with special needs whom the mother didn't feel would be able to complete the requirements for the study on her own). The percentage of eligible mothers who provided contact information for one or more age-eligible daughters was 66%.

Train Research Associate for interviewing: Months 14-15 – We trained a total of four graduate student research interviewers. Three were originally trained, but one had to drop out after doing four interviews because of the burden of her graduate studies. A second interviewer also had serious medical problems which interfered with her being able to complete the last several interviews assigned to her. All interviewers had prior academic coursework on qualitative interviewing and had conducted research using qualitative methods. Each interviewer read the study protocol and discussed the project aims with Dr. Patenaude. Questions were answered regarding the nature of the study population, *BRCA1/2* genetic testing and screening

and surveillance recommendations for mutation carriers, the extent of probing demanded by the interview schedule, respect for autonomy of subjects and their rights to not answer or to discontinue the interview. Interviewers were trained in persistence and call strategies necessary to reach and schedule the interviewees and were provided with information about preferred times for contact for each subject. They were also extensively trained in the handling of any subject distress which might arise and had 24-hour contact information for the PI and project RA (both mental health professionals), both of whom were informed of when interviews were being conducted.

Monitor interview quality and consistency: Months 16-22 - All interviewers read two transcripts of Dr. Patenaude, the PI, conducting project pilot interviews. The first three interviewers conducted a pilot interview which was listened to with the PI at length for suggestions about improvements in the approach to questions and handling of follow-up questions. By the time the last interviewer joined the project, all pilot interviews had been conducted, so she could not do a pilot interview. She was a highly experienced interviewer, however, and she listened to the tape of Dr. Patenaude conducting a project pilot interview and went over it in detail with Dr. Patenaude before conducting her own first interview on this project. All first interviews were listened to together by Dr. Patenaude and the interviewer for suggestions about improvement. As needed, additional interviews were listened to with Dr. Patenaude until it was felt that interviewer quality was established.

TASKS TO BE COMPLETED BY END OF MONTH 26:

Conduct interviews: Months 16-26 – Thirty-nine subject interviews which averaged 56 minutes in length were conducted via telephone. One additional interview will be conducted in the next several weeks once the 40th subject has been consented and completed her questionnaire. These interviews required an average of five phone calls each to schedule with this highly mobile, busy group of young adults. The interviews were all conducted in one session. One subject reported minor distress, but, when followed up with a phone call from the PI, the subject said she was fine and no further distress was noted by the PI. Many subjects found the interview helpful or interesting. All subjects who initiated an interview completed the interview and no topics were omitted.

Develop database and Enter Quantitative data: Months 12-26 – Quantitative responses of all 39 subjects have completed participation in the project have been entered into the database and are ready for further statistical analysis. The quantitative data from our 40th participant is currently pending, as we are in the process of recruiting this final daughter. Data from our 40th participant will be entered as soon as it becomes available. We have a biostatistician, Dr. Julie Aldridge, of the Dana-Farber Department of Biostatistics ready to help us conduct these analyses.

Transcribe interviews: Months 16-26 - Interviews are being transcribed by Cambridge Transcriptions, an experienced transcription company which does local court recordings and transcribes for other major research universities in the Boston area. In addition, they are providing us with digital records of the interviews and Larissa Hewitt, the project RA, is listening to the digital recording to insert or correct any missing or incorrectly transcribed

material. This should guarantee that the transcription is a highly accurate record of the conversation which took place during the telephone interview.

Develop Coding Manual: Months 24-26– Using Atlas-ti, the coding manual is being developed. The PI is coding a number of pilot and project interviews, creating and editing the code book as she proceeds. These codes will be discussed with the research team to ensure that they will allow us to answer all of the questions we propose to answer with this research. We will then hone down the final Code Book which will be used to train the coders. The project interviews which were used to develop the Code Book will be recoded along with the remaining interviews.

Hire and Train Coders: Months 25-26– We will utilize currently employed staff to code the interviews. Training will involve the review of the codes with Dr. Patenaude to make sure there is a shared understanding of their meaning and limits. Coders will then code 1-2 training interviews from the group of pilot interviews. These will be reviewed and discussed with the interviewers. Coding of the first several project interviews will also be discussed with Dr. Patenaude to ensure reliability and consistency of the application of codes.

TASKS TO BE COMPLETED MONTHS 27-36:

Coding of interviews: Months 17-23: Revised expected period: Months 26-28

Analyze Coded data: Months 17-26: Revised expected period: Months 27-29

Integrate qualitative and quantitative data: Months 24-28: Revised expected period: Months 29-30.

Work with consultants to develop Educational Intervention: Months 25-30 – We will discuss our study findings and plans for development of the educational intervention with Drs. Tung, Ryan, Garber, Partridge and Tercyak and to enlist their suggestions for the nature and format of the intervention to be developed.

We have also had initial discussions with Dr. Catherine Coleman of the Dana-Farber/Harvard Cancer Center Health Communications Core and have ascertained that they will help us with the graphics and written communication of materials in our draft educational intervention for 18-24 year old daughters of *BRCA1/2* mutation carriers. This group has an extensive history of working with medical researchers and interventionists to maximize the accessibility, readability, attractiveness, and utility of interventions for targeted groups of at-risk individuals.

Pilot educational intervention: Months 31-35 – We will enroll 10 additional subjects to review and provide reaction to the pilot educational intervention which we are developing. Responses will be gathered through a telephone interview process similar to the methods employed in our qualitative interviews. These phone interviews are expected to take approximately 30 minutes.

Write Journal articles, Research reports, parent brochure or web content: Months 25-36 – We look forward to the preparation of manuscripts from our project data. We are beginning to

outline the papers we will plan to write to report anticipated and unanticipated project findings. We will present data from our study in oral presentation to the IMPAHC meeting (the International Meeting on Psychosocial Aspects of Hereditary Cancer) in Amsterdam in April 2011 (see Abstract below) and at the Era of Hope meeting in Orlando in August 2011(see Abstract below).

Plan further research: Months 34-36 – We will be seeking additional funding for gathering similar data from daughters whose mothers have died from breast cancer and will also be seeking funding for further development and testing of our breast cancer genetics educational intervention for young adult daughters of women who carry *BRCA1/2* mutations.

KEY RESEARCH ACCOMPLISHMENTS

- Established the feasibility of accessing young adult daughters of living *BRCA1/2* mutation carriers using our method of contacting them by accessing their contact information from their mothers. Compliance rate for mothers: 66%
- Conducted 39 interviews (40th participant in process of being recruited) with 18-24 year old daughters of mothers who are *BRCA1/2* mutation carriers. Established the feasibility of reaching and enrolling young adult daughters of *BRCA1/2* mutation carriers in psychosocial research. Compliance rate: 77%
- Completed assessment of breast cancer genetics knowledge, emotional distress and cancer-related distress among 39 daughters of *BRCA1/2* mutation carriers (recruitment of final participant in progress).
- Scored and entered research data on quantitative assessments for 39 daughters of mutation carriers. Will initiate analysis of quantitative assessment data once 40th participant's (currently in process of being recruited) quantitative data is available.
- Transcribed 36 interviews to be completed next week. Interviews 37-40 will be transcribed as soon as the 40th interview is available and will be complete 1-2 weeks afterwards. We anticipate having 40 transcribed interviews by the end of Month 26.
- Developing coding book (to be completed within next 3 weeks).

REPORTABLE OUTCOMES

We are close to completing the final analysis of the quantitative data on this project which will only be possible once the 40th interview is conducted and we know that the data enrollment is complete. However, based on preliminary analyses, we submitted the Era of Hope Meeting abstract and an abstract for the International Meeting on Psychosocial Aspects of Hereditary Cancer (IMPAHC) in Amsterdam in April 2011 which has been accepted for oral presentation. IMPAHC is the major international meeting of the small group of researchers who study psychosocial aspects of cancer genetics, so we are excited to be able to present our study findings to this audience and we anticipate that the discussion of our work there will be useful in the final shaping of our future analyses and report writing.

Our preliminary reports show that, utilizing an established measure (Erblich et al., 2005), knowledge of daughters about hereditary breast cancer was significantly below that of women

who had undergone genetic counseling, as shown by the absence of overlap in 95% confidence intervals of the groups. Narratives confirmed knowledge about screening and risk-reduction options and recommended screening initiation age is limited. Worry about hereditary breast/ovarian cancer was high among daughters; 10% scored above the clinical cut-off of the Brief Symptom Inventory-18 (BSI-18) and 41% say they worried a great deal or to an extreme about hereditary cancer. These findings strongly suggest the need for targeted educational interventions for young women at high risk for breast and ovarian cancer due to the high likelihood (50%) of their being *BRCA1/2* mutation carriers.

We also look forward to presenting our findings at the Era of Hope meeting in Orlando in August 2011. By that time, we anticipate that our quantitative and qualitative analysis will be complete and we will present a mixed-methods report, with the narratives adding considerable depth and specificity to the findings, which will, in turn, impact the development of the draft educational intervention which we will be pilot testing in Year 3.

CONCLUSION

We have established the feasibility of reaching out to mothers who are in the *BRCA1/2* cancer registries at three teaching hospitals and, through contact information they provided, of accessing and enrolling young adult daughters of *BRCA1/2* mutation carriers for psychosocial studies in hereditary cancer. This study involved quantitative and qualitative measures of the young women's knowledge of breast cancer genetic testing and of their own hereditary cancer risks, their attitudes towards information acquisition about hereditary breast cancer and *BRCA1/2* genetic testing, and their knowledge of and plans to utilize (or not utilize) recommended screening strategies or risk-reduction options. Preliminary analyses suggest that there are significant gaps in essential breast cancer genetics knowledge among this cohort.

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Erblich J, Brown K, Kim Y, et al. (2005). Development and validation of a breast cancer genetic counseling knowledge questionnaire. Patient Education and Counseling 56, 182-191

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APPENDICES – Study Abstracts, Questionnaires, and Interview.

ABSTRACT FOR ERA OF HOPE MEETING

What Do Young Adult Daughters of *BRCA* Mutation Carriers Know about Hereditary Risk and How Much Do They Worry

Background and Objectives: Daughters of *BRCA1/2* mutation carriers have a 50% chance of inheriting cancer risks up to 85% for breast cancer (often early onset) and 60% for ovarian cancer. Genetic testing and uptake of enhanced screening remains sub-optimal, especially for 25-40 year old mutation carriers (Botkin, 2003; Claes 2005). Accurate knowledge is a prerequisite to informed decision making and adherence to health recommendations. We lack data on what young, at-risk women know about their risks and recommended screening/risk-reduction measures and about their anxiety related to hereditary cancer. These data are needed for development of targeted educational materials to improve timely screening initiation and risk-reducing interventions which could reduce morbidity and, ultimately, mortality in this high-risk group. A health educational intervention which provides high-risk women who are 18-24 years old with the knowledge and skills they need to adopt active coping and health-affirming screening methods at the earliest appropriate age could ultimately save lives.
The objectives of our project are to 1)Describe in-depth the genetic knowledge, attitudes, health behaviors, and life plans of 40 daughters, ages 18-24 years, of mothers who are *BRCA1/2* mutation carriers, and 2)Define specific health educational, psychological, insurance and medical needs of this population.
Methodology: Thirty-four daughters (aged 18-24 years) of living *BRCA1/2*-positive mothers (mothers previously tested at one of 3 Harvard hospitals) completed written questionnaires including the Brief Symptom Inventory-18 (BSI-18), Impact of Event Scale (hereditary cancer as the event), and Breast Cancer Genetic Counseling Knowledge Questionnaire (BGKQ) and qualitative telephone interviews about their knowledge of hereditary breast/ovarian cancer risk and screening and risk-reduction surgeries, worry about hereditary cancer and the impact of their mother's genetic status on their future planning, including plans for genetic testing.
Results to Date: 38 daughters have enrolled to date and 34 have completed participation. Participation rate is 70%. Participants were an average of 21 years of age; the majority were either college students or college graduates. 88% were single. Six had mothers with no cancer history, 5 mothers had ovarian cancer, 22 had breast cancer, and one mother had had breast and ovarian cancer. Phone interviews averaged 56 minutes in length.
Knowledge of daughters about hereditary breast/ovarian cancer genetics was significantly below that of women who had undergone genetic counseling, as shown by the absence of overlap in the 95% confidence intervals of the groups' responses to a standardized instrument. Narratives confirm knowledge is limited about screening and risk-reduction options, including age at which cancer screening should be initiated. Worry about hereditary breast/ovarian cancer was high among daughters; 15% scored above the clinical cut-off of the BSI-18 and nearly half said they worried a great deal or to an extreme about hereditary cancer.
Conclusion: Young, high-risk women have little knowledge about the probabilities and options for managing the cancers for which their risks are remarkably increased. Educational interventions may reduce their anxiety about hereditary breast/ovarian cancer, and ultimately

improve their participation in effective screening and risk reducing interventions that improve survival and quality of life.

Abstract for International Meeting on Psychosocial Aspects of Hereditary Cancer (IMPAHC)

What Do Young Adult Daughters of *BRCA1/2*+ Mothers Know about Hereditary Risk;How Much Do They Worry?

Authors: **Andrea Farkas Patenaude Ph.D.**[1]*, Nadine Tung M.D.[2], Paula Ryan M.D.[3], Larissa Hewitt M.S.W.[1], and Judy E. Garber M.D., M.P.H.[1]
Affiliations: 1: Dana-Farber Cancer Institute, Boston MA USA 2: Beth Israel-Deaconess Medical Center, Boston MA USA, 3: Massachusetts General Hospital, Boston MA USA

Introduction: Daughters of *BRCA1/2* mutation carriers have 50% chance of inheriting cancer risks up to 85% for breast cancer (often early onset) and 60% for ovarian cancer. We lack data on what young at-risk women know about their risks and recommended screening/risk-reduction measures and data on their anxiety about hereditary cancer. Data are needed for development of targeted educational materials to improve timely screening initiation and risk-reducing interventions which could reduce morbidity and, ultimately, mortality in this high- risk group.
Methods: Thirty-four daughters (aged 18-24 years) of living *BRCA1/2* -positive mothers (mothers previously tested at one of 3 Harvard hospitals) completed written questionnaires and qualitative telephone interviews about their knowledge of hereditary breast/ovarian cancer risk and screening and risk-reduction surgery, worry about hereditary cancer and the impact of their mother's genetic status on their plans for counseling/testing.
Results: Utilizing an established measure (Erblich et al., 2005), knowledge of daughters about hereditary breast cancer was significantly below that of women who had undergone genetic counseling, as shown by the absence of overlap in 95% confidence intervals of the groups. Narratives confirm knowledge is limited about screening and risk-reduction options and recommended screening initiation age. Worry about hereditary breast/ovarian cancer was high among daughters; 15% scored above the clinical cut-off of the Brief Symptom Inventory-18(BSI-18) and nearly half say they worried a great deal or to an extreme about hereditary cancer.
Conclusion: Targeted interventions are needed to educate young, high-risk women about screening and to reduce anxiety about hereditary cancer.
*Presenting author

QUESTIONNAIRE FOR PARTICIPANTS

THANK YOU FOR PARTICIPATING IN THIS STUDY. PLEASE FILL OUT THIS FORM AND RETURN IT IN THE ENCLOSED ENVELOPE

Today's Date (please fill in): _____

Demographics

1. Date of birth: Month: _____ Day: _____ Year: 19_____

2. Current age: _____ years old

3. Gender: ☐ Male ☐ Female

4. Race: (Check all that apply)

☐ White ☐ Black or African American ☐ Asian

☐ American Indian/Alaska Native ☐ Native Hawaiian/ Pacific Islander

5. Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Education

6. Highest grade in school: (Check one that applies)

☐ Finished elementary or middle school

☐ High school graduate or equivalent Year graduated:_____

☐ Some college Years attended:_____

☐ College graduate -Year graduated____ Degree_____ Major:_____

☐ Post-graduate Degree: Degree _____ Field _____

☐ Other (please explain) _____

Employment

7. Occupation: _____

8. Current employment: (Check all that apply)

- ☐ Employed full time
- ☐ Employed part time
- ☐ Full time Student
- ☐ Part time Student
- ☐ Homemaker full time
- ☐ Retired
- ☐ Not employed- seeking work
- ☐ Not employed – not seeking work

Home & Family

9. Do you have sisters? (circle one) Yes No

If yes, how many?_____

If yes, how old are your sisters?_____

10. Do you have brothers? (circle one) Yes No

If yes, how many?_____

If yes, how old are your brothers?_____

11. Marital status:

- ☐ Single
- ☐ Married; Spouse's Occupation _____
- ☐ Living as Married; Partner's Occupation _____
- ☐ Separated
- ☐ Divorced
- ☐ Widow or Widower

12. If currently married: Years Since Marriage_____

13. If currently married: Spouse's **Education**

Highest grade in school: (Check one that applies)

☐ Finished elementary or middle school

☐ High school graduate or equivalent

☐ Some college

☐ College graduate

☐ Post-graduate Degree:

☐ Other (please explain) _____

14. I live most or all of the year: (Check one that applies)

☐ With parents, grandparents, brothers or sisters

☐ With wife, husband or partner

☐ In dorm, with or without a roommate

☐ With a roommate in apartment or house

☐ Alone

☐ Other_____

15. Household income:

☐ Under 20,000 per year

☐ Between 21,000 and 50,000 per year

☐ Between 51,000 and 100,000 per year

☐ Between $101,000-$149,000 per year

☐ Over $150,000 per year

☐ Don't know

☐ Don't want to say

16. Do you have children? ☐ Yes ☐ No - If no, please skip to Question **22**.

17. Number of children you have: (Please check one)

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 or more

18. Current age of daughter(s): _____

19. Current age of son(s): _____

20. Are any of these children step-children?

☐ Yes - If yes, please circle age(s) of step-child(ren) above.

☐ No

21. Are any of these children adopted?

☐ Yes - If yes, please underline age(s) of adopted child(ren) above.

☐ No

22. If it were up to you would you plan to have more children than you currently have sometime in your life? (please answer whether or not you currently have children)

☐ Yes

☐ No

Family History of Cancer

Please tell us about ANYONE in your family who has ANY type of cancer. We are interested in any cancer in a **blood relative**. A maternal relative is a blood relative on your mother's side of the family. A paternal relative is a blood relative on your father's side of the family.

23. Please tell us about the following blood relatives.

Relative	**Had Cancer?** (circle one)	**Type(s) of Cancer**	**Their Age at Diagnosis**	**Your Age when he/she Diagnosed**	**Is he/she currently living?** (circle one)	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
Mother	Yes or No				Yes or No	Yes No DK
Maternal grandmother	Yes or No				Yes or No	Yes No DK
Maternal grandfather	Yes or No				Yes or No	Yes No DK
Father	Yes or No				Yes or No	Yes No DK
Paternal grandmother	Yes or No				Yes or No	Yes No DK
Paternal grandfather	Yes or No				Yes or No	Yes No DK

24. Have any of your sisters ever had cancer? (circle one)

Yes No N/A (I don't have a sister)

For each blood-related **sister** who had cancer, list the type(s) of cancer, her age when the cancer was found, your age at that time and answer the other two questions.

Sister	**Type(s) of Cancer**	**Her Age at Diagnosis**	**Your Age when her cancer was found**	**Is she currently living?** (circle one)	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
1				Yes or No	Yes No DK
2				Yes or No	Yes No DK
3				Yes or No	Yes No DK
4				Yes or No	Yes No DK

25. Have any of your brothers had cancer? (circle one)

Yes No N/A (I don't have a brother)

For each blood-related **brother** who had cancer, list the type(s) of cancer, his age when the cancer was found, your age at that time and answer the other 2 questions.

Brother	**Type(s) of Cancer**	**His Age at Diagnosis**	**Your Age when his cancer was found**	**Is he/she currently living? (Circle one) (DK=Don't know**	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
1				Yes or No	Yes No DK
2				Yes or No	Yes No DK
3				Yes or No	Yes No DK
4				Yes or No	Yes No DK

26. Do you have any other blood relatives who have had cancer? This could include aunts (sisters of your mother or father) or uncles (brother of your mother or father) or cousins.

☐ Yes ☐ No- Skip to Question 27.

For each of your other blood relatives, who had cancer, list how he or she is related to you (your maternal aunt, paternal uncle, maternal first cousin, etc.), the type(s) of cancer, how old he/she was when the cancer was found and your age when their cancer was found.

Relation to you	**Type(s) of Cancer**	**His/Her Age at Diagnosis**	**Your Age when cancer was found**	**Is he/she currently living? (Circle one) (DK=Don't know**	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
1.				Yes No DK	Yes No DK
2.				Yes No DK	Yes No DK
3.				Yes No DK	Yes No DK
4.				Yes No DK	Yes No DK

Insurance

27. I have: (Check one that applies)

☐ Health insurance through my work

☐ Health insurance through my spouse's work

☐ Health insurance through my parents

☐ Health insurance from another source: _____

☐ No health insurance

28. I have:

Disability insurance ☐ Yes ☐ No ☐ Don't know

Life insurance ☐ Yes ☐ No ☐ Don't know

29. Do you think you have ever been denied or had difficulty getting any type of insurance due your family history or a known predisposition to cancer?

☐ Yes - If yes, please explain below. ☐ No

Personal Medical History

30. Do you have any significant health problems?

☐ Yes- If yes, please list below ☐ No

_____

_____

Concerns about Cancer & Heredity

31. Do you think the cancer in your family was due to an inherited predisposition to cancer in your family?

☐ Definitely not ☐ Probably not ☐ Don't know ☐ Probably ☐ Definitely was

32. How much do you worry about cancer risk being inherited in your family?

☐ Not at all ☐ A little ☐ Quite a bit ☐ A great deal ☐ To an extreme

33. How much do you worry about getting cancer in the future?

☐ Not at all ☐ A little ☐ Quite a bit ☐ A great deal ☐ To an extreme

34. How much you would say you worry about whether your child/children (present or future children) will develop cancer in the future?

☐ Not at all ☐ A little ☐ Quite a bit ☐ A great deal ☐ To an extreme

Discussion with Professionals

35. Have you ever spoken to any of these professionals about cancer and heredity? (Check all that apply)

☐ Internist/Primary Care Doctor

☐ Gynecologist

☐ Oncologist

☐ Other doctor_____

☐ Your child's pediatrician

☐ Genetic counselor/Geneticist

☐ Nurse

☐ Social Worker

☐ Psychotherapist

☐ Others (who?) _____

☐ NONE OF THE ABOVE

36. Have you ever:

Had Cancer Genetic Counseling	☐ Yes	☐ No	☐ Don't know
Had Genetic Testing for cancer gene	☐ Yes	☐ No	☐ Don't know
Gotten cancer genetic test result	☐ Yes	☐ No	☐ Don't know
If tested, test result was	☐ Positive	☐ Negative	☐ Indeterminate

BREAST CANCER GENETICS QUESTIONNAIRE

Please answer all of the questions below. Feel free to say you don't know. Genetic medicine is a new field and many professionals are taking courses to learn about the genetic advances in recent years. So, please do not feel badly if you are not sure of all the answers. But please do try to give one answer for each item.

CIRCLE THE ANSWER YOU BELIEVE IS CORRECT:

	True	False	Don't Know
1.50% of inherited genetic information (about breast cancer risk) is passed down from a person's mother.	True	False	Don't Know
2. 25% of inherited genetic information (about breast cancer risk) is passed down from a person's father.	True	False	Don't Know
3. There is more than one gene that can increase the risk of breast cancer.	True	False	Don't Know
4. A woman who has a sister with a breast cancer gene mutation has a 1 in 4 chance of having a gene mutation herself.	True	False	Don't Know
5. A father can pass down a breast cancer gene mutation to his daughters.	True	False	Don't Know
6. One in 10 women has a breast cancer gene mutation.	True	False	Don't Know
7. All women who have a breast cancer gene mutation will get cancer.	True	False	Don't Know

If the currently available genetic tests were to indicate that a woman has a breast cancer gene mutation, she is at increased risk for:

8. Breast cancer	True	False	Don't Know
9. Ovarian cancer	True	False	Don't Know
10. Lung cancer	True	False	Don't Know
11. Bladder cancer	True	False	Don't Know

If a woman who already had breast cancer was found to have a breast cancer gene mutation, she is at increased risk for developing:

12. Another breast cancer	True	False	Don't Know
13. Ovarian cancer	True	False	Don't Know
14. Lung cancer	True	False	Don't Know
15. Bladder cancer	True	False	Don't Know
16. Women who test positive for breast cancer mutations are generally more likely to develop breast cancer at a young age	True	False	Don't Know

17. A man who carries a breast cancer gene mutation has an increased risk of developing breast cancer himself. True False Don't Know

18. If a woman tests positive for a breast cancer gene mutation, her male relatives' risk for developing prostate cancer are lowered. True False Don't Know

19. A woman may be at greater risk for developing ovarian cancer if she has several close relatives with ovarian cancer. True False Don't Know

20. A woman may be at greater risk for developing ovarian cancer if she has several close relatives with breast cancer. True False Don't Know

21. A woman who has her healthy ovaries removed will definitely not get ovarian cancer. True False Don't Know

22. A woman who has her breasts removed will definitely not get breast cancer. True False Don't Know

23. Screening for ovarian cancer often does not detect a tumor until it is more advanced. True False Don't Know

Directions: Please check one answer for each question #24-27.

24. How many copies of a non-working breast cancer gene must one inherit to be at inherited risk for breast cancer?

a. 0
b. 1
c.3
d. Don't know

25. What is the approximate risk that the average women in the United States will develop breast cancer in her lifetime:

a. 12%
b. 24%
c. 58%
d. 72%
e. Don't know

26. If a genetic test were to indicate that a woman inherited a breast cancer gene mutation, then how likely is she to develop breast cancer in her lifetime?

a. Up to 15% chance
b. Up to 25% chance
c. Up to 40% chance
d. up to 50% chance
e. up to 85% chance
f. Don't know

27. Select the procedure that is NOT appropriate for the detection of ovarian cancer:

a. ultrasound
b. pap smear
c. CA-125 blood test
d. pelvic examination
e. Don't know

Directions:
Indicate how frequently each of these comments was true for you during the past seven days in relation to **inherited predisposition to breast/ovarian cancer.** Please **circle the word that best fits your experience over the past 7 days.**

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.	Not at all	Rarely	Sometimes	Often
2. I avoided letting myself get upset when I thought about it or was reminded of it.	Not at all	Rarely	Sometimes	Often
3. I tried to remove it from memory.	Not at all	Rarely	Sometimes	Often
4. I had trouble falling asleep or staying asleep because of thoughts about it that came into my mind.	Not at all	Rarely	Sometimes	Often
5. I had waves of strong feeling about it.	Not at all	Rarely	Sometimes	Often
6. I had dreams about it.	Not at all	Rarely	Sometimes	Often
7. I stayed away from reminders of it.	Not at all	Rarely	Sometimes	Often
8. I felt as if it hadn't happened or wasn't real.	Not at all	Rarely	Sometimes	Often
9. I tried not to talk about it.	Not at all	Rarely	Sometimes	Often
10. Pictures about it popped into my head.	Not at all	Rarely	Sometimes	Often
11. Other things kept making me think about it.	Not at all	Rarely	Sometimes	Often
12. I tried not to think about it.	Not at all	Rarely	Sometimes	Often
13. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	Not at all	Rarely	Sometimes	Often
14. Any reminder brought back feelings about it.	Not at all	Rarely	Sometimes	Often
15. My feelings about it were kind of numb.	Not at all	Rarely	Sometimes	Often

THIS PAGE WILL BE SEPARATED FROM THE QUESTIONNAIRE WHEN RECEIVED

Could you please tell us when it would be best for us to try to reach you to schedule our phone interview for this project:

Best times:_____

Best days:_____

Phone numbers: Please give us your phone numbers and tell us if it ok to call that number to reach you

Day:_____ ☐ ok to call

Evening or weekends:_____ ☐ ok to call

Cell:_____ ☐ ok to call

THANK YOU.

PLEASE RETURN TO US <u>WITH ONE SIGNED COPY OF THE CONSENT FORM</u> IN THE STAMPED ENVELOPE PROVIDED.

Return to:

Dr. Andrea Patenaude
Dana-Farber Cancer Institute
44 Binney Street
Boston, MA 02115

TELEPHONE INTERVIEW SCHEDULE FOR PARTICIPANTS

PARTICIPANT NUMBER: _____ INTERVIEWER:_____

DATE: _____

START TIME: _____ END TIME: _____

INTERVIEW LENGTH (MINUTES): _____

FIRST, THANK YOU VERY MUCH FOR YOUR WILLINGNESS TO PARTICIPATE IN THIS INTERVIEW.

THE GOAL OF THIS PROJECT IS TO LEARN AS MUCH AS WE CAN ABOUT HOW YOUNG WOMEN WHOSE FAMILIES HAVE BEEN AFFECTED BY CANCER OR THE RISK OF CANCER THINK ABOUT RISKS FOR THEMSELVES AND OTHERS AND HOW THEY THINK ABOUT THEIR OWN HEALTH. WE ARE HOPING THAT YOU CAN HELP US TO PLAN HOW TO TALK TO OTHER YOUNG PEOPLE YOUR AGE ABOUT THESE THINGS.

WE ARE VERY INTERESTED IN YOUR THOUGHTS AND OPINIONS, SO PLEASE TAKE AS LONG AS YOU LIKE TO ANSWER OUR QUESTIONS.

I WOULD LIKE TO SAY AGAIN THAT YOU ARE FREE NOT TO ANSWER ANY QUESTION YOU DON'T WANT TO ANSWER AND YOU CAN ALSO STOP THE INTERVIEW AT ANY TIME. ALSO, FEEL FREE TO SAY I DON'T KNOW AT ANY POINT. WE DO NOT EXPECT THAT YOU WILL KNOW THE ANSWERS TO ALL THE QUESTIONS WE ASK.

BEFORE WE BEGIN, ARE THERE ANY QUESTIONS YOU WOULD LIKE TO ASK ME?

GENERAL INFORMATION- CURRENT STATUS

1. First, Can you please start by telling me a bit about yourself, about your life currently – where are you in school or work, what do you think about for your future, what's most important to you now?
2. How do you think about your own health now?
3. Do you think at all about insurance – health, life, disability? If so, what do you think?, do?
4. Do you do anything in particular to try to stay healthy? If yes, What do you do?

CANCER

1. Would you say that cancer runs in your family?
2. How you would say cancer or the risk of getting cancer has affected your family?

3. How much do you worry about getting cancer yourself?

   What triggers your worries?

   What is your specific worry, if any?

   Do you tell anyone about that worry?

4. How much do you worry about other people in your family getting cancer (or getting cancer again?) Who do you worry about?

5. Who in your family has had genetic testing for cancer genes?

Relationship	gene tested	when done	result	Subject's reaction

FINDING OUT

1. How did you find out that your mother (or other relatives) had been tested?

   Probes, if not clear:
   Did you go with your mother when she was tested?

   When she got her result?

   Whenever daughter was informed:
   What exactly were you told?

   How old were you?

   Do you know what gene she was tested for? And what was found?

   How long after your mother knew the result?

   Who was present when you were told? Who spoke?

   Do you remember what went through your head as you were being informed?

   How did you react immediately?

   Later?

   When has it come up subsequently? How often? What brings it up?

2. Did the person informing you have any particular message they were trying to get across about the meaning of this information either for themselves or for you? If yes, what message? How did you feel about that message?

3. How do you now think about the meaning or importance of this information to you?
   Probe: Did this information change how you think about cancer and your family?
   (Clarify if not clear, if daughter herself has been tested and, if so, how that changed meaning or importance of the genetic information for her)

4. What type or types of cancer does this information relate to for you or for other members of your family?

5. Did having this information (either mother's result or, if tested herself, mother's and her result), change any of your thinking about your future, either what you might want to do or the timing of what you plan to do?

TALKING WITH OTHERS

1. Were you given any guidelines about people to talk to or not talk to about it?

   Whom have you talked with about this information? How have these discussions gone?

   Probes:

   a. Mother

   b. Father

   c. Sisters

   d. Brothers

   e. Other relatives

   f. Friends

   g. Significant Other

2. Have you talked to any medical professionals about inherited cancer risk?

   If no: has it just not come up or did you choose not to speak about it?

   If yes: who did you talk to , how did it come up , about what, how did you feel about those conversations?

3. Have you spoken to anyone else who is in a position similar to yours, i.e. having a tested relative? How was that for you? Would it be helpful?

4. Was there anyone you wanted to speak to about this who you haven't been able to talk to?

   If yes: whom? why wasn't it possible?

5. Have there been times when you wanted to hear **less** about genetics or genetic testing or related matters, when you wished people didn't talk about it to you so much?

   If yes: could you tell us about those times?

6. Are there things you wish you knew or understood better about this area?

   Things you wish you didn't know or feel you would have been better off not knowing?

7. Based on your own experience, what do you think is the ideal age or time for parents to talk to their children about their own hereditary cancer risk or test results?

THINKING ABOUT COUNSELING AND TESTING

1. How old were you when you learned that there was testing YOU could have at some point in your life which could tell you about your own hereditary cancer risks?

   How did you feel about testing then?

   How now?

   How much do you think about testing?

2. Have your parents given you advice about getting tested, either whether to have it or when to have it?

   Has anyone else talked to you about genetic testing for yourself?

3. Have you ever spoken to a genetic counselor?

   If yes: how did that come about? Who went? How was it for you? What did you learn?

   If no,: did you ever want to? Would you know how to find a genetic counselor?

4. Have you ever seen any ads on TV or in magazines about testing for hereditary cancer genes?

   If yes: what effect, if any, did the ads have on you?

5. **If clear subject has been tested, skip to Q. 7.** What do you think now about getting tested?

   Do you have a clear idea of what you want to do? If so, what?

   What are the pros and cons?

   Thoughts about testing later on in life? Never?

   Need more info to decide? Where would you get that info?

6. If she decides she wants to be tested, is there an age or a time in a woman's life when it would be ideal for her to get testing?

7. **If not tested, skip to Q. 9b.** How did your testing come about? How did it feel to wait for results? Have you gotten results? What was your reaction to results?

   If got results: how did you feel about your result?

   If not gotten results: do you have a plan for getting them or just not now?

8. Whom have you told about your test result? Family? Friends? Doctors?

9. a. Is there an age or a time in a woman's life when it would be ideal for her to get testing?

   b. **(SKIP TO HERE)** What do you think should be the youngest age at which people with hereditary cancer risk in their family should be able to be tested to see if they carry that increased risk (minimal age)? Why?

10. Do you think there should be genetic counseling for kids before the age when they can usually be tested to answer questions about genetic risk?

    If yes: how should it work?

HEALTH BEHAVIORS

1. When do you go to a doctor?
   Probes:
   How often?

   what type?

   Do you feel like your doctor really knows you?

   Do your doctors know about hereditary risk in your family? your result **(if appropriate)**?

2. Has anyone talked to you about things that you can do to try to prevent cancer either now or in the future?

   If no: skip to Q. 3.

   If yes:
   Who?

   What?

   When?

   How did you feel when these things were brought to your attention? (**Probe:** Hopeful, Avoidant or Other feelings)

   How often do you think about these things?

   How do you feel when you think about those things now?

3. **(SKIP TO HERE)** Do you do anything to try to prevent cancer that is related to knowledge of hereditary cancer risk?

4. At what age do you think you will start having mammograms?

   How often would you plan to have them then?

   How would you arrange to have a mammogram?

   How do you think they will get paid for?

5. Is there anything else you know of that a woman who might be at hereditary risk for cancer might do to reduce her risk of cancer?

6. Are there/were there things that your mother or other relatives have done/did to try to prevent cancer?

   Do you know other people who are doing special screening or other things because of having hereditary cancer risk?

   How did you feel about their doing those things?

   Does their experience influence your thoughts about what you might do?

7. Have you ever heard of any of the following? **If yes, what have you heard about them?**

   Breast MRIs

   Clinical breast exams

   Breast self-examination

   Prophylactic or risk-reducing mastectomy

   Prophylactic or risk-reducing oophorectomy

   CA-125 test

   Transvaginal ultrasound

HEREDITY IN THE NEWS

1. Where do you get most of your information about hereditary cancer or genetic testing?

2. How often do you come upon an article or program about cancer and genetics? Do you typically read it or listen or not? How do you find the level of the information?

FUTURE RESOURCES

1. How much do young people who are from families with increased hereditary cancer risks want to know about the risk and their options? When and how should it be discussed?

2. Would it be helpful if there were an information source geared specifically to young people who might have such hereditary risk?

   If not: why not?

   If so: what format would be best (written brochure, video, Internet website, other)?

   What should it include?

   Not include?

   Who should deliver the message?

   Can you imagine a situation where you might use this information source?

RESPONSE TO PARTICIPATION Subject Feedback Section

Thank you for taking the time to participate in this interview. Now I would just like to ask you a few more questions about how it was for you to participate in this interview.

1. How have you felt answering these questions today?

2. Did you feel distressed in any way by any aspect of participating in this study?

   If yes- Can you tell me a bit about what caused you distress? How distressing was it?

3. Did you find participating in this interview helpful in any way?

   If yes- In what way(s)

4. Were there any questions you didn't like or that we could have asked in a better way?

   If yes- Which questions?

5. Are there important questions for cancer survivors related to cancer and heredity which we have left out?

6. Is there anything that you would like to know more about that we talked about or touched on today?

Thank you. (Turn off tape recorder).

Confirm address as to where the honoraria should be sent.

END TIME: _____